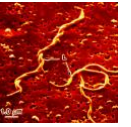
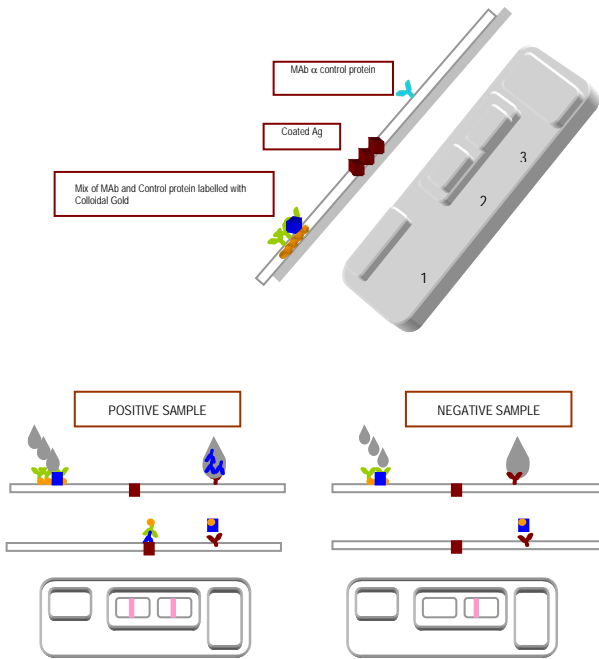


INGEZIM LYME-CROM (Ab)

R.15.LY.K41



Ingezim LYME-CROM is based on an indirect immunocromatography assay technique, which uses specific antibodies for canine immunoglobulins, and a recombinant antigen of *B.burgdorferi*.



TECHNICAL BASIS OF THE KIT

The device consists of a plastic casing with three windows:

- **Window1:** Where the Monoclonal Antibody specific of canine IgG and the Control Protein are conjugated to colloidal gold particles.
- **Window2:** Where the inactivated antigen of *B. burgdorferi* is adsorbed.
- **Window 3:** Where the MAb specific to the control protein is attached to indicate the validation of the assay.

APPLICATION

Detection of specific antibodies to *B. burgdorferi* in canine sera or plasma samples.

INTERPRETATION OF THE RESULTS

Positive sample: Red/pink lines in the Test zone and in the Control zone. **Negative sample:** Only a red/pink line in the Control zone. **Not valid assay:** No line in the Control zone

SENSITIVITY AND SPECIFICITY

Correlation with IFA technique

105 samples from dogs previously classified by IFI were analyzed by INGEZIM LYMECROM. The results obtained indicated that the correlation between both techniques was **96.1%**.

COMPOSITION OF THE KIT

- Diagnostic devices individually wrapped
- Diluent tubes, to prepare the dilution of the sera samples
- Dropper bottle dilution buffer
- Disposable tips



PRODUCT DISTRIBUIDO BY INGENASA



SHELF LIFE: **24 months**
Stored: 4°C-25°C

Ed. 020217

INMUNOLOGIA Y GENETICA APLICADA, S.A.



INGEZIM LYME-CROM

Prod Ref: 15.LY.K4

Ensayo inmunocromatográfico para la detección de Anticuerpos (IgM e IgG) frente a *Borrelia burgdorferi* en suero, plasma o sangre de perro.

Immunocromatographic test kit for the detection of IgM and IgG antibodies to *Borrelia burgdorferi* in dog serum, plasma or whole blood.

Ultima revisión / Last revision: 16/09/2014 (R1-09/05/14)

Esta versión del protocolo ha sido modificada.



Changes on the insert have been made.

COMPOSICION DEL KIT
KIT COMPOSITION

Reactivo Reagent	PRESENTACION KIT
	PRESENTATION OF THE KIT
	12 Test
Dispositivos de diagnóstico envasados individuales en bolsas de aluminio Diagnostic devices individually wrapped in aluminium bags.	12
Gotero con Tampón de cromatografía en volumen suficiente para la realización de las pruebas Chromatographic buffer dropper bottle	1
Puntas de pipetas amarillas para micropipetas Disposable pipettes tips	12
Micropipeta volumen fijo 10 µl Micropipette of 10 µ	1

I. TECHNICAL BASIS

Ingezim Lyme-crom is a rapid immunochromatographic assay designed for the detection of antibodies to *Borrelia burdorferi* using a recombinant protein immobilised to the solid phase membrane..

II. STORAGE:

All the reagents must be kept between 18 and 25 °C.

IMPORTANT! DO NOT FREEZE

III. PRECAUTIONS:

1. Read carefully the instructions of use.
2. **Kept the reagents at room temperature before their use.**
3. Do not mix reagents or instruction from different kits.
4. Avoid any contamination of the reagents.
5. Do not use the kits after the expiry date.
6. There should be no eating, drinking or smoking where specimens or kit reagents are being handled.
7. Do not pipette by month.

IV. TEST PROCEDURE:

1. Preparing the test device:

Remove the test device from the protective pouch and place it on a flat surface.

NOTE : Do not remove the device from the pouch until ready to use.

2. Sample addition:

Gently mix the sample by inverting. Place 1 tip on the precision pipette and aspirate 10 µl of sample (serum, plasma or whole blood). Depressing bottom of the pipette to dispense the sample into window "S" (sample). Make sure as much of the sample is applied as possible.

Serum or plasma: Fresh, or stored at 2°-7° C, may be used in this test. Serum or plasma may be stored for up to 5 days at 2°-7° C. For longer storage, samples should be frozen.

Whole blood: Must be anticoagulated (EDTA, heparin, etc...) and may be used either fresh or after refrigeration for up to 5 days. It is important that

the sample does not be left in the pipette tip too long as clotting may occur. In this case it is important to have the device ready in advance.

Previously frozen or older samples must be centrifuged before use.

PRECAUTION: *Never touch the nitrocellulose membrane with the pipette.*

3. Solution buffer addition:

Holding the diluent bottle vertically, promptly add 2 drops of the buffer to the window "S".

4. Read and interpretation:

After 10-15 minutes read the results.

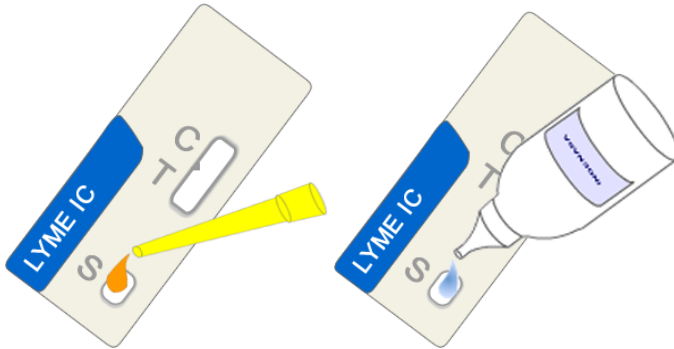
POSITIVE RESULTS: the test is positive if two coloured bands appear. One band will appear in the window "T" (Test line) and one in the window "C" (Control line).

NEGATIVE RESULT: There is no line in the window "T" (Test line) and there is a purple coloured line in the window "C" (control line).

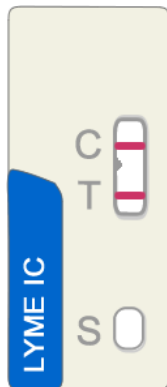
NO VALID TEST: If there is no line into the window "C" the assay can't be considered valid and should be repeated.

Coloured bands, which appears after 15 minutes are not diagnostic, and should be ignored.

Add 10 µl of sample and 2 drops of buffer solution into the window "S"



Wait 10-15 minutes and read:



POSITIVE



NEGATIVE

Developed and manufactured in Spain by:

Distributed in SPAIN by:



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